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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,281	08/22/2006	Lucio Filippini	163-711	8075
7590 James V. Costigan Hedman & Costigan 1185 Avenue of the Americas New York, NY 10036-2646	02/26/2010		EXAMINER RICCI, CRAIG D	
			ART UNIT 1628	PAPER NUMBER
			MAIL DATE 02/26/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,281	FILIPPINI ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 November 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-8 and 10-22 is/are pending in the application.
 4a) Of the above claim(s) 5,7,8 and 13-21 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4, 6, 10-12 and 22 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Status of the Claims

1. The amendments filed 11/02/2009 were entered.

Response to Arguments

2. Applicants' arguments, filed 11/02/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1-4, 6, 10-12 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Cowie* (cited in a previous Action), *Sorenson* (cited in a previous Action), *Miyachi et al* (cited in a previous Action) and *Greene et al* (cited in a previous Action).**

6. Instant claim 1 is drawn to a blend comprising two or more compounds wherein Applicant has elected (A) the copper salt of acetylsalicylic acid and (B) micronized titanium dioxide, which reads on claims 1-4, 6, 10, 12 and new claim 22. More specifically, as recited by instant claim 11, the particles of the micronized titanium dioxide have a particle size lower than 1 micron. Thus, as discussed above, the elected invention reads on instant claims 1-4, 6, 10-12 and 22.

7. As discussed in the previous Action mailed on 6/09/2009, and which is reiterated largely as follows, compositions, such as sunscreens, comprising micronized titanium dioxide having a particle size lower than 1 micron are well known in the art and are specifically taught, for example, by *Cowie* (Column 1, Lines 10-12, and Column 1, Lines 35-37). However, *Cowie* does not teach a blend which also comprises copper acetylsalicylic acid as recited by the instant claims.

8. *Sorenson* discloses that organic copper complexes and especially copper (II) acetylsalicylic acid (Column 4, Lines 65-68) exhibits superoxide dismutase activity, acts as a superoxide scavenger and is useful as a radioprotectant (Abstract) which can be administered topically (Column 3, Lines 59). Although *Sorenson* does not teach copper (II) acetylsalicylic acid for use in a sunscreen, *Miyachi et al* teach that sunburn cell formation is prevented by scavenging oxygen intermediates such as superoxide using superoxide dismutase (Abstract; Page 307, Figure 1). Furthermore, it is well known in the art, and specifically taught by *Greene et al*

that sunscreen formulations comprising superoxide dismutase as an antioxidant protect the skin from UV radiation (Page 6, Lines 3-18). Thus, although *Sorenson* does not teach copper (II) acetylsalicylic acid for use in a sunscreen, the skilled artisan, in view of *Sorenson*, would have recognized that copper (II) acetylsalicylic acid exhibits superoxide dismutase activity, acts as a superoxide scavenger and is useful as a radioprotectant, and would have reasonably predicted that copper (II) acetylsalicylic acid would protect the skin against UV damage similar to superoxide dismutase as taught by *Miyachi et al* and *Greene et al*. Accordingly, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to formulate a sunscreen comprising copper (II) acetylsalicylic acid in view of *Miyachi et al* with a reasonable expectation of success. In particular, the skilled artisan would have found it *prima facie* obvious to substitute copper (II) acetylsalicylic acid as taught by *Sorenson* in place of in place of superoxide dismutase in the sunscreen formulation taught by *Greene et al*. The simple substitution of one known antioxidant (i.e., superoxide dismutase) with another (i.e., copper (II) acetylsalicylic acid having superoxide dismutase activity) according to known methods to provide predictable results is *prima facie* obvious.

9. Furthermore, it would have been *prima facie* obvious to formulate a sunscreen comprising micronized titanium dioxide and copper (II) acetylsalicylic acid in view of *In re Kerhoven*, 626 F.2d 846 (CCPA 1980). As stated in MPEP 2144.06, “It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846 (CCPA 1980). Thus, in the instant case, it would have been *prima*

Art Unit: 1628

facie obvious to combine micronized titanium dioxide and copper (II) acetylsalicylic acid, both of which are taught as useful in sunscreen formulations, to form a third composition to be used for the very same purpose.

10. Applicant, however, traverses on two grounds. First, Applicant argues that “[n]othing in Cowie suggests the combination of any two of salicylic acid (ESA), an promoting compound (PRO) and a modulating compound (MOD) as pointed out in claim 1” (Applicant Argument, Page 10). Similarly, Applicant argues that *Miyachi et al* is “not suggestive of the use of copper acetylsalicylate as a sunscreen” (Applicant Argument, Page 11) and *Green* provides “no suggestion that these compositions are useful in combination with copper acetylsalicylate” (Applicant Argument, Page 12). Yet, Applicants are reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091 (Fed. Cir. 1986). In the instant case, as discussed above, the rejection is based on combinations of references, not on *Cowie* alone, *Miyachi et al* alone, or *Green* alone. Accordingly, Applicant’s arguments are not found persuasive.

11. Next, Applicant argues that “[t]he Sorenson patent mentions that copper acetylsalicylate and analogous compounds are useful in protecting mammalian cells from damage due to gamma or X-radiation. The effect is postulated as being due to a superoxide dismutaste activity of these compounds” (Applicant Argument, Page 11). However, “the superoxide dismutaste activity of copper acetylsalicylate is different from the activity of natural superoxide dismutaste” (Applicant Argument, Page 11). Thus, Applicant argues that it would not have been obvious to use copper acetylsalicylate in combination with *Cowie*. Yet, turning to *Sorenson*, it is actually disclosed that

(due to the differences asserted by Applicant) copper acetylsalicylate “has the potential of being ***much more effective*** than Cu-Zn SOD [i.e., natural superoxide dismutase]” (Column 6, Lines 57-60; emphasis added). As such, the fact that "the superoxide dismutase activity of copper acetylsalicylate is different from the activity of natural superoxide dismutase" would not have dissuaded a skilled artisan from the combination discussed above but, rather, would have further motivated said combination with the reasonable expectation that the differences in copper acetylsalicylate would “facilitate tissue distribution and cellular membrane transport” (Column 7, Lines 3-5) not possible for natural superoxide dismutase, thereby making copper acetylsalicylate a more effective superoxide scavenger and antioxidant.

12. For the foregoing reasons, Applicant’s arguments are not considered persuasive. Accordingly, instant claims 1-4, 6, 10-12 and new claim 22 are rejected as *prima facie* obvious.

Conclusion

The new ground(s) of rejection presented in this Office action are necessitated by Applicant’s amendments to the claims. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan "Paddy" Sreenivasan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1628

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642